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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,206	07/29/2003	Kei Roger Aoki	17328CON4	1996

7590 05/09/2005

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,206	AOKI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1,4,5,9,12,13 and 28-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,4,5,9,12,13 and 28-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the preliminary amendment filed July 29, 2003, claims 2, 3, 6-8, 10, 11 and 14-27 have been cancelled, claims 1 and 12 have been amended, and new claims 28-32 have been added. Therefore, claims 1, 4, 5, 9, 12, 13 and 28-32 are examined.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 4, 5 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U. S. Patent 6,113,915. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 4, 5 and 9 in the instant application disclose a method for treating pain, the method comprising administration of a botulinum toxin to a mammal. This is obvious variation in view of claims 1-12 of the patent which disclose a method for treating pain, comprising intraspinal administration of a therapeutically effective amount of a botulinum toxin to a mammal. Both sets of claims cite a method of treating pain, comprising administration (e.g., intraspinal administration) of a botulinum toxin. Thus, claims 1, 4, 5 and 9 in present application and

claims 1-12 in the patent are obvious variations of a method of treating pain, comprising administration of a botulinum toxin.

3. Claims 1, 4, 5, 9, 12, 13 and 28-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 28-34 of co-pending application 10/630,204. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 4, 5, 9, 12, 13 and 28-32 in the instant application disclose a method for treating pain, comprising administration such as peripheral administration of a botulinum toxin to a mammal. This is obvious variation in view of claims 1, 4, 5, 9, 12, 13 and 28-34 of the co-pending application which disclose a method for treating joint pain or arthritis, the method comprising administration such as peripheral administration of a botulinum toxin to a mammal. Both sets of claims cite a method of treating pain such as joint pain or arthritis pain, comprising administration such as peripheral administration of a botulinum toxin. Thus, claims 1, 4, 5, 9, 12, 13 and 28-32 in present application and claims 1, 4, 5, 9, 12, 13 and 28-34 in the co-pending application are obvious variations of a method of treating joint pain, comprising administration of a botulinum toxin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1, 4, 5, 9, 12, 13 and 28-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 11/003,677 (amendment filed December 3, 2004). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 4, 5, 9, 12, 13 and 28-32 in the instant application disclose a method for treating pain, the method comprising

administration such as peripheral administration of a botulinum toxin to a mammal. This is obvious variation in view of claim 1 of the co-pending application which disclose a method for treating pain, comprising peripheral administration of a botulinum toxin to a mammal, wherein the pain is not associated with a muscle spasm. Both sets of claims cite a method of treating pain, comprising administration such as peripheral administration of a botulinum toxin. Thus, claims 1, 4, 5, 9, 12, 13 and 28-32 in present application and claim 1 in the co-pending application are obvious variations of a method of treating pain, comprising administration of a botulinum toxin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4, 5, 9, 12, 13 and 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1, 4, 5, 9, 12, 13 and 28-32 are indefinite because the claims lack essential steps in the method for treating pain. The omitted steps are the effective amount of a botulinum ttoxin used and/or the outcome of the treatment. Claims 4, 5, 9, 13, 28-30 and 32 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

7. Claim 9 is indefinite because of the use of the term "substantially alleviated". The term "substantially alleviated" renders the claim indefinite, it is not clear to what extent the pain is alleviated because neither the specification nor the claim defines the term.

8. Claim 32 is indefinite because the claim is dependent from a non-existing claim, claim 33.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1, 4, 5, 9, 12, 13, 28, 31 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by Binder (WO 95/30431).

Binder teaches a method of reducing headache pain such as vascular headache pain (migraine, Table 1(a)) or a headache pain of neuralgia (Table 1(b), page 1, lines 21-27) by

administering a therapeutically effective amount of a presynaptic neurotoxin such as botulinum toxin A in mammals including humans (page 5, line 25-page 6, line 16; Example I; claims 1, 4, 5), where the neurotoxin can be administered extramuscularly or subcutaneously at a localized site of pain (page 9, lines 15-21; claims 12, 13, 28, 31 and 32) and the effect to produce paralysis at target sit muscles for up to 3 to 6 months (page 11, lines 6-13; claim 9).

10. Claims 1, 4, 5, 9, 12, 13 and 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoki *et al.* (WO 95/17904).

Aoki *et al.* disclose a method of treating pain related to spasticity and dystonia, low back pain, myofascial pain or sports injuries using a botulinum toxin such as sero type A, B, C, D, E, F, and G (page 1, lines 7-16; page 5, lines 5-7; Examples 7, 8, 9; claims 1, 4, 5), where the toxin can be administered by intramuscular injection into a local area or subcutaneous injection, which can deliver the toxin directly to the affected area (page 7, lines 11-20; claims 12, 13, 28-32), and the effect of the toxin will last weeks to several months (page 17, lines 6-7; claim 9).

11. Claims 1, 4, 5, 9, 12, 13 and 28-32 are rejected under 35 U.S.C. 102(e) as anticipated by First (U.S. Patent 6,063,768, filing date: September 4, 1997).

First teaches a method of treating a neurogenic inflammatory disorder such as inflammatory arthritis or rheumatoid arthritis by administering a therapeutically effective amount of a botulinum toxin (e.g., sero type A, B, C, D, E, F, and G), which alleviates the unpleasant side effect of neuropathic pain that is due to the release of certain neuroinflammatory peptides and other mediators of inflammation, in response to injury/inflammation or disease (column 5, line 48-column 6, line 67), where the botulinum toxin can be administered subcutaneously or intramuscularly at or near the site of inflammation, including a joint or joints (column 7, lines

29-36; claims 1, 4, 5, 12, 13 and 28-32). The reference also indicates botulinum toxin has a long lasting therapeutic effect (e.g., weeks or months, column 7, lines 1-8; claim 9).

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
April 29, 2005